



Enforcement of Unlicensed Pharmaceutical Distribution: Obstacles, Solutions, and Prosecutor's Perspective

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Abstract: This article examines the challenges prosecutors face when handling illegal pharmaceutical cases and proposes strategic solutions to enhance law enforcement effectiveness. The study identifies several key obstacles, including a lack of technical expertise among prosecutors regarding health law, weak coordination with institutions such as the Food and Drug Supervisory Agency (BPOM) and the police, and limited infrastructure, particularly the absence of accredited forensic laboratories. Additionally, existing regulations are deemed inadequate as they fail to provide sufficient deterrents, with penalties for illegal pharmaceutical activities often being too lenient relative to the harm caused. Low public participation in reporting violations and monitoring the distribution of illegal pharmaceuticals further exacerbates these issues. To address these challenges, the study recommends strengthening technical capacity through specialized training for prosecutors, establishing dedicated specialist units within the prosecutor's office, and enhancing institutional coordination through clear cooperation protocols. Furthermore, the adoption of information technology to create an integrated supervision system and revising regulations to impose stricter sanctions on illegal pharmaceutical actors are suggested as effective measures. The study concludes that a comprehensive approach, involving institutional reform, cross-sectoral collaboration, and public education, is essential for reinforcing the role of the prosecutor's office. Implementing these strategies is expected to significantly improve law enforcement effectiveness in the pharmaceutical sector and sustainably protect public health, thereby contributing both practically and academically to the enhancement of legal and health systems.

Keywords: Circulation of Pharmaceutical Preparations; Distribution Permit; Prosecutors

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1. Introduction

Health is a fundamental human right and a crucial element of welfare that must be realized in alignment with the ideals of the Indonesian nation as outlined in Pancasila and the 1945 Constitution of the Republic of Indonesia. Health issues are a significant concern for all countries, both developed and developing like Indonesia, because health is a key determinant of a nation's progress and a fundamental human right. The government is obligated to provide health services as part of its commitment to fulfilling the community's health needs, as stated in Article 5 of Law Number 36 of 2009 concerning Health. Health services encompass not only the provision of healthcare facilities and professionals but also the supply of medicines, as regulated in Article 36 Paragraph (1) of the same law.¹

The Food and Drug Supervisory Agency (BPOM) was established to oversee the surveillance of drugs and food, aiming to detect, prevent, and supervise the circulation of these products. However, the distribution of pharmaceutical preparations without proper permits has become a complex issue within Indonesia's health and legal systems. Illegal pharmaceutical products pose significant threats to public health due to the risk of harmful side effects and undermine the integrity of the legitimate pharmaceutical industry. Data from BPOM indicate a rising trend in the discovery of illegal pharmaceutical preparations, highlighting the persistence of this problem.²

The proliferation of illegal drugs has widespread negative impacts, including increased health risks for consumers and potential economic losses for the state due to rampant illegal trade. In this context, the prosecutor's office plays a central role in ensuring that such violations are addressed effectively and fairly in accordance with applicable regulations. Legally, the prosecutor's office has the strategic responsibility to act decisively against these violations to protect public health and maintain public trust in the justice system.³

However, the prosecutor's office faces numerous obstacles in handling illegal pharmaceutical cases. Technical challenges, such as difficulties in obtaining valid laboratory evidence and a limited pool of human resources with expertise in health law, hinder effective prosecution. Additionally, inadequate coordination between the prosecutor's office, BPOM, and the police slows down the legal process. These structural barriers not only diminish the effectiveness of law enforcement but also erode public trust in efforts to eliminate illegal pharmaceuticals. The continued

¹ Ega Nurrahman Dewi, Lola Yustrisia, and Syaiful Munandar, "Tuntutan Jaksa Penuntut Umum Terhadap Pelaku Tindak Pidana Peredaran Obat Keras Yang Tidak Memiliki Izin Edar", *Sumbang* 1, no. 2 (January 2023): 33–40.

² Heri S.Widodo Amaniyah, "Analisis Yuridis Terhadap Pengawasan Sediaan Obat yang tidak Memiliki Izin Edar pada Saat Pandemi Covid-19 di Indonesia", *Jurnal Kolaboratif Sains* 5, no. 8 (2022): 586–602, <https://doi.org/10.56338/jks.v5i8.2736>.

³ Nurul Hasanah and Feny Windiyastuti, "Sanksi Hukum Bagi Pelaku Pengedar Sediaan Farmasi Tanpa Izin", *Jurnal Kewarganegaraan* 6, no. 2 (2022): 3009–13, <https://doi.org/10.31316/jk.v6i2.3243>.

circulation of illegal drugs in Indonesia underscores the vulnerability of the country's defenses against threats to public security.⁴

To address these challenges, it is essential to enhance the institutional capacity of the prosecutor's office. This can be achieved through specialized training programs for prosecutors in health and pharmaceutical law, developed in collaboration with academics and industry practitioners. Establishing dedicated specialist units within the prosecutor's office to focus on illegal pharmaceutical cases can also improve internal competence and the effectiveness of case handling. Furthermore, developing clear cooperation protocols between BPOM, the National Police, and the prosecutor's office is crucial for streamlining investigations and prosecutions.⁵

Strategic measures to combat the circulation of unlicensed drugs include increasing institutional capacity, optimizing inter-agency coordination, and updating regulations. Implementing technology-based solutions, such as an integrated information system for real-time monitoring and detection of illegal pharmaceutical distribution, can significantly enhance law enforcement capabilities. Additionally, revising existing regulations to impose stricter sanctions on illegal pharmaceutical actors will provide a stronger deterrent against such activities.⁶

Public education and preventive approaches are equally important in addressing the issue of illegal pharmaceuticals. Raising public awareness about the dangers of consuming illegal pharmaceutical products can reduce market demand. Public campaigns utilizing social media and digital platforms can effectively communicate the risks associated with illegal drugs and emphasize the importance of purchasing pharmaceuticals from legitimate sources. Empowering community participation through accessible technology-based reporting systems and incentivizing whistleblowers can further aid in the detection and reporting of illegal activities.

Revisions to existing regulations should focus on strengthening health law and BPOM technical regulations with more specific provisions regarding the role of the prosecutor's office and mechanisms for cross-agency coordination. Enhanced enforcement of sanctions against illegal pharmaceutical distributors will reinforce the deterrent effect of the law. Additionally, evidence-based research should underpin every policy decision, requiring collaboration between prosecutors, academics, and

⁴ Abdul Hamid, "Penegakkan Hukum Terhadap Peredaran Sediaan Farmasi (Kosmetik) Tanpa Izin Edar Dari BPOM RI Di Provinsi Riau"," *Jurnal Equitable* 3, no. 3 (2018): 77-94, <https://doi.org/10.37859/jeq.v3i2.1172>.

⁵ Gunawan Nachrawi and Christiyanti Dewi, "Penegakkan Hukum Terhadap Pelaku Tindak Pidana Pengekar Sediaan Farmasi Tanpa Izin Edar (Studi Kasus Putusan Pengadilan Nomor: 351/Pid.Sus/2018/PN SMn)"," *Justitia Jurnal Hukum* 6, no. 2 (October 1, 2024): 176-89, <https://doi.org/10.30651/justitia.v6i02.8422>.

⁶ Adrianty Charmelita Valentine Mali and Rosalind Angel Fanggi Deddy.R.CH.Manafe, "Alasan Pemberatan Hukuman dalam Tindak Pidana Memproduksi dan Mengedarkan Obat Tanpa Izin Edar di Kabupaten Kupang," *TERANG: Jurnal Kajian Ilmu Sosial, Politik dan Hukum* 1, no. 4 (58/Pid.Sus/ /Pn 2020): 43-52, <https://doi.org/10.62383/terang.v1i4.596>.

research institutions to develop adaptive recommendations for the pharmaceutical sector.⁷

A comprehensive and sustainable approach is necessary to overcome existing obstacles and enhance the effectiveness of law enforcement in eradicating the distribution of pharmaceutical preparations without permits. Strengthening the prosecutor's office through institutional reforms, cross-sectoral collaboration, and public education will not only improve legal protections but also bolster public trust in Indonesia's legal and health systems. By fostering synergy between law enforcement, education, and research, Indonesia can more effectively and sustainably address the circulation of illegal pharmaceuticals, thereby ensuring a stronger and more equitable health and legal system.⁸

2. Method

Research is a scientific approach based on a certain method, systematics and thinking that has the purpose of studying certain legal phenomena by analyzing the object being studied.⁹ This study uses a normative legal research method that aims to analyze obstacles and solutions in the enforcement of the circulation of pharmaceutical preparations without a distribution permit by the prosecutor's office from a regulatory perspective. The normative research was chosen because the main focus of this research is to examine the applicable laws and regulations, including the implementation of criminal law in illegal pharmaceutical cases, as well as the relationship between pharmaceutical regulations and the effectiveness of their enforcement by the prosecutor's office.

The research data is in the form of primary, secondary, and tertiary legal materials. Primary legal materials include laws and regulations such as Law Number 36 of 2009 concerning Health, Law Number 8 of 1981 concerning the Criminal Procedure Law, and technical regulations from the Food and Drug Supervisory Agency (BPOM). Secondary legal materials consist of scientific literature, legal journals, BPOM annual reports, and related policy documents. Meanwhile, tertiary legal materials, such as legal dictionaries and encyclopedias, are used to strengthen understanding of concepts and terminology.

The analysis was carried out with a prescriptive approach, where the research focused on formulating legal solutions that could be applied to overcome obstacles in the enforcement of illegal pharmaceutical cases. The analysis technique uses a deductive method, starting from an understanding of legal theory and the concept of law

⁷ Diana Ndun, Orpa Ganefo Manuain, and Rosalind Angel Fanggi, "Dasar Pertimbangan Hakim dalam Putusan Nomor 150/PID.SUS/2021 Terhadap Pongedar Sediaan Farmasi Tanpa Ijin dalam Perspektif Keadilan (Studi Kasus Putusan Pengadilan Negeri Kupang)", *Terang : Jurnal Kajian Ilmu Sosial, Politik dan Hukum* 1, no. 4 (November 20, 2024): 108–17, <https://doi.org/10.62383/terang.v1i4.617>.

⁸ Leonardo Cahyo Nugroho, "Tanggung Jawab Hukum Pelaku Usaha Farmasi Terhadap Izin Edar Obat", *Jurnal Juristic* 1, no. 2 (2020), <https://doi.org/10.35973/jrs.v1i02.1650>.

⁹ Zainuddin Ali, *Metode Penelitian Hukum* (Sinar Grafika, 2021).

enforcement, then followed by the decomposition of applicable regulations to assess the extent to which its implementation is able to overcome existing problems.

3. Obstacles and Law Enforcement

Enforcing laws against the circulation of pharmaceutical preparations without distribution permits in Indonesia encounters significant technical and institutional challenges. A primary obstacle is the lack of technical expertise among law enforcement officials, particularly prosecutors, regarding pharmaceutical regulations and evidentiary procedures. Many prosecutors have not received specialized training in health and pharmaceutical law, limiting their ability to interpret laboratory evidence and assess the legality of pharmaceutical products effectively. Additionally, the reliability of laboratory evidence is compromised by the limited capacity and accreditation of forensic laboratories, resulting in delays and weakened legal cases against perpetrators.¹⁰

Coordination deficiencies between the prosecutor's office, the Food and Drug Supervisory Agency (BPOM), and the police further hinder effective law enforcement. The absence of integrated cooperation protocols leads to overlapping authorities and delays in case handling, often resulting in lost or contaminated evidence. This inefficiency not only slows the legal process but also diminishes public trust in the enforcement system, allowing illegal pharmaceutical activities to persist. Moreover, the existing legal framework lacks adequate deterrents, as sanctions for illegal pharmaceutical distribution are often insufficient and primarily administrative, such as fines, which do not match the severity of the public health risks involved.¹¹

Structural issues, including an inadequate number of prosecutors dedicated to illegal pharmaceutical cases and a lack of technological support for monitoring and reporting, exacerbate these challenges. The minimal use of integrated information systems impedes real-time tracking and efficient case management, while low public awareness and participation in reporting violations sustain high demand for illegal pharmaceuticals. To address these issues, strategic solutions are necessary. These include enhancing the technical capacity of prosecutors through specialized training, establishing dedicated specialist units within the prosecutor's office, and developing clear cooperation protocols between BPOM, the police, and prosecutors. Implementing technology-based solutions, such as integrated information systems,

¹⁰ Afifah Naurah Nasution et al., "Tindak Pidana Mengedarkan Sediaan Farmasi Tanpa Izin Edar Menurut UU No. 36 Tahun 2009 Tentang Kesehatan (Studi Putusan Nomor: 739/Pid.Sus/2014/PT-Mdn)," *Doktrina: Journal of Law* 3, no. 2 (November 30, 2020): 99-107, <https://doi.org/10.31289/doktrina.v3i2.3945>.

¹¹ Wirna Rosmely Defrianto, "Penegakkan Hukum Pada Tingkat Penyidikan Terhadap Pelaku Tindak Pidana Pengedaran Sediaan Farmasi Tanpa Izin Di Kota Solok," *Unnes Journal Of Swara Justisia* 3, no. 1 (September 3, 2019): 182-93.

and revising regulations to impose stricter sanctions on illegal pharmaceutical actors are also critical.¹²

Furthermore, public education campaigns to raise awareness about the dangers of illegal pharmaceuticals and encourage community participation in supervision are essential. Empowering the public through accessible reporting systems and incentivizing whistleblowers can significantly aid in detecting and reducing illegal pharmaceutical distribution. Additionally, evidence-based research and international collaboration can provide valuable insights and support the development of effective policies. By adopting a comprehensive and sustainable approach that includes institutional reforms, cross-sectoral collaboration, and public education, Indonesia can strengthen the prosecutor's office, enhance law enforcement effectiveness, and protect public health more effectively. This integrated strategy is vital for building a stronger, more equitable health and legal system, ultimately fostering greater public trust in Indonesia's legal and health institutions.¹³

4. Strategic Solutions to Strengthen the Role of the Prosecutor's Office

Strengthening the role of the prosecutor's office in prosecuting cases involving the circulation of pharmaceutical preparations without distribution permits requires a strategic, systematic, and sustainable approach. A primary solution is to enhance technical capacity through specialized training for prosecutors handling illegal pharmaceutical cases. This training should provide an in-depth understanding of health law, pharmaceutical regulations, and scientific evidence-based evidentiary procedures. Collaborating with academics, BPOM, and international institutions with expertise in this field is essential to bolster the technical competence of prosecutors.¹⁴

In addition to training, establishing a specialist unit within the prosecutor's office is urgently needed. This unit should focus on handling illegal pharmaceutical cases using a multidisciplinary approach that includes prosecutors, pharmacists, and laboratory analysts. The creation of such a specialist unit will not only improve the efficiency of case handling but also strengthen the accountability of the prosecutor's office in protecting the public from the threats posed by illegal pharmaceuticals

¹² Asliani Harahap, "Penegakan Hukum Pidana Terhadap Pelaku Dengan Sengaja Menjual Sediaan Farmasi Tanpa Izin Edar", *Juris Studia: Jurnal Kajian Hukum* 1, no. 1 (June 2020): 1-6.

¹³ Aryo Putrawan Polamolo, Moh Rusdiyanto U. Puluhalawa, and Suwitno Yutye Imran, "Peran Kepolisian Dalam Menanggulangi Tindak Pidana Pengedaran Obat Secara Illegal (Studi Kasus Polres Gorontalo Kota)", *Student Scientific Creativity Journal (SSCJ)* 1, no. 4 (June 18, 2023): 431-64, <https://doi.org/10.55606/sscj-amik.v1i4.1745>.

¹⁴ Dewi Purwaningsih and Anggita AtikaWidiastut, "Sanksi Pidana Terhadap Pemilik Apotik Terhadap Penjual Obat Daftar Secara Ilegal", *Jatijajar Law Review* 2, no. 2 (September 2023): 134-44.

circulating without proper distribution permits or being distributed by individuals lacking expertise in the field.¹⁵

Effective coordination between institutions is crucial. Developing clear cooperation protocols between the prosecutor's office, BPOM, and the National Police is necessary. These protocols should include integrated workflows, efficient data exchange mechanisms, and a strict division of roles and responsibilities. Enhanced coordination can reduce overlapping authorities and accelerate the investigation and prosecution processes. Additionally, the implementation of an integrated information system that facilitates real-time data exchange between BPOM, the police, and the prosecutor's office can significantly improve the identification and tracking of illegal pharmaceutical products. This technology can also assist the prosecutor's office in managing case databases, monitoring case progress, and analyzing violation trends to formulate more adaptive policies.¹⁶

Regulatory revisions play a vital role in this strategy. Existing regulations need to be strengthened with more specific provisions regarding the procedures for combating illegal pharmaceuticals, including imposing heavier sanctions to provide a stronger deterrent effect. For instance, introducing additional criminal sanctions for distributors or sellers who knowingly distribute illegal products can increase legal pressure on illegal pharmaceutical distribution chains.¹⁷

A preventive approach through public education is equally important. Increasing public awareness about the risks of using illegal pharmaceuticals through extensive campaigns involving various media, including social media and digital platforms, is essential. These campaigns should educate the public on how to recognize legitimate products, the dangers of illegal products, and the importance of purchasing pharmaceuticals from authorized pharmacies. Furthermore, encouraging public participation in supervising the distribution of illegal pharmaceuticals is crucial. Developing technology-based reporting systems, such as mobile applications, can enable the public to report suspected violations quickly and easily. Providing incentives or awards for credible whistleblowers can enhance public involvement in efforts to eradicate pharmaceutical crimes.¹⁸

Support from evidence-based research is necessary to reinforce the role of prosecutors in illegal pharmaceutical cases. Collaboration with universities and research

¹⁵ Andi rahmah and Nur fahmi Nurmiati, "Tinjauan Yuridis Tindak Pidana Sediaan Farmasi (Obat) Secara ilegal Di Kota Makassar (Studi Putusan 1670/Pid.Sus/2021/PN.Mks)," *Pledoi Law Journal* 1, no. 2 (July 6, 2023): 71–87.

¹⁶ Andin Rusmini, "Tindak Pidana Pengedaran Dan Penyalahgunaan Obat Farmasi Tanpa Izin Edar Menurut Undang-Undang Nomor 36 Tahun 2009 Tentang Kesehatan," *Al'Adl Jurnal Hukum* VIII, no. 3 (September 2016): 23–44, <https://doi.org/10.31602/al-adl.v8i3.674>.

¹⁷ Dini Wininta Sari, Echwan Iriyanto, and Fiska Maulidian Nugroho, "Pertimbangan Hakim Dalam Tindak Pidana Pengedaran Sediaan Farmasi Obat Tramadol," *Jurnal Komisi Yudisial* 1, no. Mei 12, 2022 (n.d.): 65–81, <https://doi.org/10.29123/jy.v15i1.524>.

¹⁸ Amaniyah, "Analisis Yuridis Terhadap Pengawasan Sediaan Obat yang tidak Memiliki Izin Edar pada Saat Pandemi Covid-19 di Indonesia". "

institutions can produce empirical studies that offer insights into pharmaceutical crime trends and the effectiveness of law enforcement efforts. The findings from such studies can inform the prosecutor's office in developing more effective and data-driven strategies.

Moreover, the prosecutor's office should cultivate closer relationships with the international community. Learning from best practices in countries that have successfully addressed the circulation of illicit pharmaceuticals can inspire the development of local policies. Cross-border information exchange and training can strengthen the institutional capacity of the prosecutor's office to tackle global challenges related to illegal pharmaceuticals. This crime violates Law Number 36 of 2009 concerning Health, which explicitly prohibits the distribution of medicines without a valid permit from relevant authorities.¹⁹

By integrating these solutions, the prosecutor's office can enhance its role as a leader in prosecuting illegal pharmaceutical cases. This structured, technology-based, and collaborative approach is expected to overcome existing obstacles while providing better protection for the public from the risks associated with pharmaceutical products lacking distribution permits. Successful implementation of these strategies will not only increase the effectiveness of law enforcement but also strengthen public trust in Indonesia's legal system.²⁰

5. Conclusion

This study identifies various obstacles in the prosecution of cases of circulation of pharmaceutical preparations without a distribution permit by the prosecutor's office, including limited technical understanding of prosecutors, weak coordination between institutions, lack of supporting infrastructure, and regulatory loopholes that reduce the effectiveness of law enforcement. This problem not only hampers the prosecution process but also allows illegal pharmaceutical criminals to continue operating, endangering public health. In this context, the prosecutor's office needs systemic strengthening in order to be able to play an optimal role in enforcing the law and protecting the public interest.

The strategic solutions formulated in this study emphasize the importance of increasing technical capacity through special training for prosecutors, the establishment of specialist units in the prosecutor's office, and strengthening cross-agency coordination with BPOM and the police. In addition, the use of information technology such as integrated data systems and community reporting applications can speed up the investigation process and increase public participation in the

¹⁹ Sarida Citra and Tirmizi, "Penegakkan Hukum Terhadap Pelaku Tindak Pidana Peredaran Sediaan Farmasi Berupa Obat Tanpa Izin Edar (Suatu Penelitian di Wilayah Hukum Pengadilan Negeri Medan)", *Jurnal Ilmiah Mahasiswa Bidang Hukum Pidana* 7, no. 2 (2023): 242-51.

²⁰ Dewi, Yustrisia, and Munandar, "Tuntutan Jaksa Penuntut Umum Terhadap Pelaku Tindak Pidana Peredaran Obat Keras Yang Tidak Memiliki Izin Edar".

eradication of illegal pharmaceuticals. The revision of the regulation is also an urgent step to ensure firmer sanctions and clearer legal procedures in handling this case.

The successful implementation of the solution requires a strong commitment from all stakeholders, including support from research institutions and the international community. With an integrated, data-driven, and community-engaged approach, the prosecutor's office can strengthen its role as an institution that not only enforces the law but also proactively protects public health. This research is expected to be a relevant academic contribution as well as provide a basis for more effective policies in handling illegal pharmaceutical cases in Indonesia.

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